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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,801	02/09/2006	Stuart Norman Lile Bennett	101181-1P US	3056
44992 7590 04/05/2007 ASTRAZENECA R&D BOSTON 35 GATEHOUSE DRIVE WALTHAM, MA 02451-1215			EXAMINER YOUNG, SHAWQUIA	
			ART UNIT	PAPER NUMBER
			1626	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/05/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/567,801	BENNETT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shawquia Young	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                  |                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                      | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                             | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/12/06</u> . | 6) <input type="checkbox"/> Other: _____                                                           |

## **DETAILED ACTION**

Claims 1-10 and 16-20 are currently pending in the instant application.

Claims 11-15 were cancelled by preliminary amendment.

### **I. Priority**

The instant application is a 371 of PCT/GB04/03546, filed on August 18, 2004, which claims benefit of Foreign Application UNITED KINGDOM, filed on August 22, 2003.

### **II. Information Disclosure Statement**

The information disclosure statements (IDS) submitted on June 12, 2006 and March 13, 2007 have been considered by the examiner. See Applicant's copies of the 1449.4

### **III. Restriction/Election**

#### **A. Election: Applicant's Response**

Applicants' election without traverse of Group I in the reply filed on March 13, 2007 is acknowledged. After a telephonic interview with attorney Lucy Padgett on March 13, 2007, the Examiner has included the following subject matter in claim 1 of Group I that reads "or, when n is 2, the two R<sup>1</sup> groups, together with the carbon atoms of A to which they are attached, may form a 4 to 7 membered saturated ring optionally being substituted by one or two methyl groups". Applicants cancelled claim 3 in the Remarks/Arguments filed on the March 13, 2007.

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Subject matter not encompassed by elected Group I are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

#### IV. Rejection(s)

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(1) Claims 1,2,4-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The term “prodrug” in the above claims are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1,2,4-10 and 17.

(2) Claims 1,2,4-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (1) (See pages 45-61 of the specification), does not reasonably provide enablement for a prodrug of a compound of formula (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

***The nature of the invention***

The nature of the invention is a compound of formula (1) or a pharmaceutically acceptable salt or prodrug thereof.

***The state of the prior art***

It is the state of the prior art that the term "prodrug" found in the claims is defined as a pharmacological substance (drug) which is administered in an inactive (or significantly less active) form. Once administered, the prodrug is metabolized in vivo into the active compound

(<<http://en.wikipedia.org/wiki/Prodrug>>).

***The amount of direction or guidance present and the presence or absence  
of working examples***

There is no direction or guidance present in the specification or working examples present in the specification are that defines or relates to what prodrugs are being included in the elected invention. The term "prodrug" is discussed on page 7 of the specification and reads on the following "A prodrug may be used to alter or improve the physical and/or pharmacokinetic profile of the parent compound and can be formed when the parent compound contains a suitable group or 5 substituent which can be derivatized to form a prodrug". The only example given of a prodrug is in the general sense of an in-vivo hydrolysable ester.

***The breadth of the claims***

The breadth of the claims is a compound of formula (1) or a pharmaceutically acceptable salt or prodrug thereof.

***The quantity of experimentation needed and the level of the skill in  
the art***

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with both similar and different structural radicals without any direction as to what structural radical is needed and how different the prodrug can be from a compound of formula (1).

The level of skill in the art is high without showing or guidance as to how

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to make prodrugs of a compound of formula (1) it would require undue experimentation to figure out the starting materials, solvents, temperatures and reaction times that would provide prodrugs of the above compounds.

To overcome this objection, Applicant should submit an amendment deleting the term "prodrug".

(3) Claims 1,2, 4-10 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "mono- and di-methyl derivatives" in variable  $R_{Na}$  in claim 1 is not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(4) Claim 1,2, 4-10 and 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claim 1 contains the terms "mono- and di-methyl derivatives" in the definition of  $R_{Na}$ . However, the "mono-and di-methyl derivatives" are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claim

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is indefinite.

## **V. Objections**

### ***Claim Objections***

Claim 17 is objected to because of the following informalities: the term "and" is missing between the last two compounds listed in the instant claim. Appropriate correction is required.

### ***Claim Objection-Non Elected Subject Matter***

Claims 1,2,4-10 and 17 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

## **VI. Conclusion**

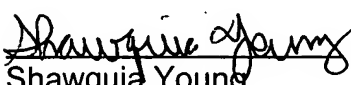
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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